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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/903,944 07/31/97 CHOU

EXAMINER

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HM22/0411

ART. UNIT	PAPER NUMBER
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FOX, D

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DATE MAILED:

04/11/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/10/00

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-45, 47-112 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 6-37, 39-45, 47-71, 73-112 is/are rejected.

☒ Claim(s) 4-5, 38, 72 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

Art Unit: 1638

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1638.

The petition under 37 CFR 1.182 of 28 December 1998 to change the order of inventors has been GRANTED. Applicants are requested to provide a substitute oath in compliance with 37 CFR 1.67(a) which lists the inventors in the new order, and also provides the complete post office and residence addresses for inventor Joyce Van Eck. The oath of 27 April 1998 was corrected in pen to change the street and zip code for that inventor, but no city was provided. In addition, the corrections were not dated, as required by 37 CFR 1.52(c).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claims 18, 52 and 77, line 3, where --of-- should be inserted before "genes"; in claim 39, penultimate line, where --and-- should be inserted after the semicolon; in claim 53, which should depend upon claim 39 and is missing a period at the end; in claims 76-78, line 1, where "method" should be replaced with --transgenic poinsettia plant-- and "second" should be deleted; in claim 101, parts (b)-(d), where --containing embryos-- should be inserted after "callus"; and in claim 111, which could depend upon claim 49 as written but could also depend upon claim 39, in keeping with the scope of similar claims.

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Claims 6-37, 39-45, 47-71, 73-96, 98-100, 102-103, 105-106 and 108-109 remain, and new claims 110-112 are, rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the production of transgenic poinsettia plants via microparticle bombardment, does not reasonably provide enablement for claims broadly drawn to any other method of making transgenic poinsettias or the plants produced therefrom. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 6-96, 98-100, 102-103, 105-106 and 108-109.

Claims 102-103, 105-106 and 108-109 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods for the regeneration of poinsettia plants via culture on the exemplified media comprising exemplified medium components, does not reasonably provide enablement for claims broadly drawn to the use of any other medium component or media for the successful regeneration of whole poinsettia plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 1-109.

Claims 1-3, 97, 101, 104 and 107 remain rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lee et al, as stated in the last office action for claims 1-4, 97, 101, 104 and 107.

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Claims 6-37, 39-45, 47-71, 73-109 and new claims 110-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheetham et al (1996) taken with Miki et al, Preil (1994) and Nataraja, as stated in the last office action for claims 1-27, 39-71 and 73-109.

Claims 73-96, 100, 102-103, 105-106, 108-109 and new claim 112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al taken with Preil (1994) and Nataraja, as stated in the last office action for claims 1-109.

Claims 4-5, 38 and 72 are deemed free of the prior art, given the unpredictability in the process as discussed above, and the failure of the prior art to teach or suggest the exemplified sequence of poinsettia regeneration media with the particularly claimed medium components, or their combination with a particle bombardment method of transformation for the successful regeneration of whole poinsettia plants.

Claims 4-5, 38 and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicants' arguments filed 10 January 2000, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection regarding the transformation method is improper, given the failure of the reference cited by the Examiner to teach *Agrobacterium tumefaciens* as newly claimed, and given the ability of other workers to obtain whole transformed

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plants following electroporation, as demonstrated by references appended to the amendment of 10 January 2000.

The Examiner maintains that *Agrobacterium rhizogenes* may be manipulated to delete the root-inducing genes, as set forth in the rejection under 35 USC 103 on page 7 of the last office action, second full paragraph. Thus, the teaching by Follansbee et al regarding the recalcitrance of *Agrobacterium*-infected *Euphorbia* plant cells to whole plant regeneration is applicable.

With regard to the references teaching electroporation newly cited by Applicants, the Examiner maintains that each reference involves a graminaceous plant species, highly unrelated to poinsettia; and also involves particular explant selection, culture and manipulation techniques not taught in the instant specification. Xu et al teach the use of halved, dehusked, germinated rice seeds (see, e.g., page 237, column 2, bottom paragraph). D'Halluin et al teach the use of immature zygotic maize embryos which have been enzymatically treated (see, e.g., page 1503, column 2, penultimate paragraph). The instant specification provides no guidance regarding these techniques, and it is unclear whether techniques useful for monocotyledonous cereal species could be applicable to the dicot poinsettia. See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicants urge that the enablement rejection regarding medium components is improper, given the amendments to the claims. The Examiner has withdrawn the rejection for claims drawn

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to plants *per se* which do not specify particular culture media, and has also withdrawn the rejection for method claims which have been newly amended. However, the claims remaining were not amended to reflect the exemplified medium additions which overcame the prior recalcitrance of *Euphorbia* to whole plant regeneration.

Applicants urge that the rejection of the claims under 35 USC 102(a) is improper, given the failure of the reference to teach the claimed sequence of media. The Examiner maintains that Lee et al (see, e.g., page 182, column 2, first full paragraph, as cited on page 5 in the last office action) teach poinsettia explant culture on a medium containing both an auxin and a cytokinin for the generation of reddish epidermal callus, followed by subculture for the formation of embryogenic callus on the medium which also contained casein hydrolysate and which would inherently contain either ammonium or nitrate salts in the MS basal salts mixture, followed by subculture on the sucrose-containing MS basal salts medium, wherein sucrose and/or the other basal salts would increase the osmotic pressure of an aqueous medium in comparison to pure water. Thus, every element of the claim is met by the reference. The claims do not specify that the callus induction medium, embryo induction medium, or developmental medium contain different components. Instead, each medium is merely characterized by a particular component and by the result of explant or callus culture thereon.

Applicants urge that the rejections under 35 USC 103 are improper, given the unpredictability inherent in the process which would preclude a reasonable expectation of success,

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and given the failure of the prior art to teach or suggest reddish epidermal callus cultured on a medium containing ammonium or nitrate salts.

The Examiner maintains that Applicants' prior refutation of the Examiner's allegations of unpredictability (see, e.g., pages 8-9 of the amendment of 10 January 2000) are in contrast to Applicants' instant reliance upon this aspect. Furthermore, the Examiner has not applied the art rejections to claims which recite the particular medium additions or transformation methods which were actually employed by Applicants to overcome the unpredictability and which provided the evidence of unexpected results, namely explant culture on an auxin- and cytokinin-containing callus induction medium to produce reddish epidermal callus, followed by culture on an embryo induction medium comprising *high* levels of nitrate, followed by culture on a developmental medium containing *high* levels of mannitol, optionally combined with microprojectile bombardment. Note that the rejected claims are not drawn to particle bombardment in combination with the exemplified medium components (claims 6-37, 39-45, 47-71, 73-109 and dependents), are not drawn to reddish epidermal callus (claims 73, 102-103 and dependents), and are not drawn to particular media or medium components (claims 73, 102-103 and dependents). See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

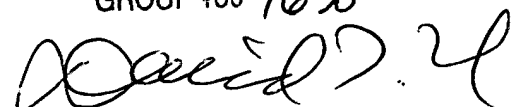
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 5, 2000

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~100~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", followed by a large, stylized flourish or number "4".